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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/076,686	02/14/2002	Yoshiharu Matahira	00225CIP/HG	2395

1933 7590 01/20/2004

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EXAMINER

OSTRUP, CLINTON T

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 01/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/076,686

Applicant(s)

MATAHIRA ET AL.

Examiner

Clinton Ostrup

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-6 and 9-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-6 and 9-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 09/558,487.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11042003. 6) ☐ Other: _____

DETAILED ACTION

Claims 4-6 and 9-25 are pending in this application.

Priority

This application is a Continuation in Part of US 09/558,487, filed April 25, 2000 and claims priority to Japanese Application Number 225245/99, filed August 9, 1999.

Response to Applicant's Arguments/Amendment

Applicant's amendment and arguments filed October 20, 2003 to the rejection of claims 1-15 under 35 U.S.C. 112, second paragraph have been fully considered and deemed persuasive. Therefore, the said rejection has been withdrawn.

Applicant's amendment and arguments filed October 20, 2003 to the Double Patenting rejection of claims 1, 4, and 5 over claims 11 and 22 of Application No. 09/558,487 have been fully considered and deemed persuasive. Therefore, the said rejection has been withdrawn.

Applicant's amendment and arguments filed October 20, 2003 to the rejection of claims 1-3 and 7-9 under 35 U.S.C. 102(b) as being anticipated by Burton et al., 5,217,962, have been fully considered and deemed persuasive. Therefore, the said rejection has been withdrawn.

Applicant's amendment and arguments filed October 20, 2003 to the rejection of claims 1-3 and 9 under 35 U.S.C. 102(a,e) as being anticipated by Murad 5,804,594, have been fully considered and deemed persuasive. Therefore, the said rejection has been withdrawn.

Applicant's amendment and arguments filed October 20, 2003 to the rejection of claims 1-15 under 35 U.S.C. 103(a) as being unpatentable over Burton et al., 5,217,962 and further in view of Matsuura et al., JP 01268618A taken together with Haynes et al., 5,998,173, have been fully considered and deemed persuasive. Therefore, the said rejection has been withdrawn.

New Claim Rejections

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of skin care, such as improving the moisture and tension of skin and the amelioration of rough skin and wrinkles it does not reasonably provide enablement for the prevention of rough skin and wrinkles. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,

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- 3) the presence or absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art,
- 7) the predictability of the art, and
- 8) the breadth of the claims.

The instant specification fails to provide guidance that would allow the skilled artisan to practice the instant invention without resorting to undue experimentation, as discussed in the subsections set forth herein below.

1. The nature of the invention, state of the prior art, relative skill of those in the art, the predictability of the art

The claimed invention relates to a method of preventing wrinkles on human skin. The relative skill of those in the art is generally that of a PHD candidate or PHD. USP 5,804,594 represents a standard publication in the art and as such is directed to those having ordinary skill in the art. USP 5,804,594 demonstrates the unpredictability of the claimed subject matter.

For example see column 1, lines 11-62, which teaches that the skin loses its functions and properties and develops wrinkles due to aging and the loss of functional properties caused by aging. Given this, it is clear that the skilled artisan would appreciate that claimed results of preventing wrinkles by orally administering a composition would be unpredictable, as aging is a natural process which occurs in time.

Given the above facts, it is clear that the art to which the instant invention relates (i.e. a method of preventing wrinkles in human skin) involves a relatively high degree of unpredictability.

2. The breadth of the claims

Claims 22-23 include the prevention of any and all wrinkles.

3. The amount of direction or guidance provided and the presence or absence of working examples

The specification provides no direction or guidance as to how the simple oral administration of a composition can be reasonably expected to prevent any and all wrinkles in the skin of a human. Moreover, in general humans have some skin wrinkles and additional wrinkles naturally develop through the aging process and although the instant application may be enabled for some methods of skin care, such as improving the moisture and tension of skin and the amelioration of rough skin and wrinkles it does

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not reasonably provide enablement for the prevention of any and all wrinkles a human has, or will develop,

4. The quantity of experimentation necessary

Applicant has provided specific examples to demonstrate that oral administration of the composition increases moisture retention and skin smoothness, but fails to provide guidance and information sufficient to allow the skilled artisan to use the invention commensurate in scope with the claims (i.e. to prevent any and all wrinkles in human skin).

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-6 and 9-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "skin beautification" in claims 4-6 and 9-25 is a relative term, which renders the claim indefinite. The term "skin beautification" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Applicant has stated that the specification is supported by the specification at page 1, second paragraph which reads:

The present invention relates to a method for skin care (or a method for promoting skin-beautification) which improves moisture and tension of skin and promotes prevention and amelioration of e.g. rough skin and fine wrinkles by orally ingesting a skin care agent containing natural-type N-acetylglucosamine).

and page 4, the fourth full paragraph, which reads:

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In a preferred embodiment of the present invention, the skin care agent comprises chitinoligosaccharide and the above-mentioned natural-type N-acetylglucosamine, wherein the chitinoligosaccharide is contained in an amount of from 0.1 to 20 % by weight and the natural-type N-acetylglucosamine is contained in an amount of from 0.1 to 99.9 % by weight. The skin care agent may further contain an ingestible carrier, as the case requires.

Upon consideration of these paragraphs, it is clear that there is support for "a method for promoting skin-beautification," however, the metes and bounds of the term "skin beatification" are not clear.

The phrase "skin beautification" renders the claims indefinite because it is unclear what is encompassed by the term "skin beautification." Thus, the term "skin beautification" renders the claims indefinite because it is unclear what is encompassed by the term "skin beautification."

Any remaining claims are rejected as depending on indefinite base claims.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 5-6,13-15,17,19, 23, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murad 5,804,594 and further in view of BIKEN CORP JP 10165138.

Murad teaches N-acetylglucosamine in an orally administered pharmaceutical composition for the treatment of skin conditions, including the treatment of skin wrinkles, by administering said composition in the form of capsules and tablets and containing amounts of N-acetylglucosamine that overlap those as claimed instantly in claims 5-6

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and 19. See: col.1, line 25 – col. 3, line 56; col. 8, line 43 – col. 10, line 40, claims 13-19.

Although the primary reference teaches N-acetylglucosamine in an orally administered pharmaceutical composition for the treatment of skin conditions, including the treatment of skin wrinkles, it lacks the collagen peptide as claimed instantly in claims 5-6.

BIKEN CORP teaches a health food which has various beauty making and health effects, such as ameliorating rough, dry skin and fine wrinkles comprising hyaluronic acid, chondroitin sulfate, collagen, nucleic acid, and docosahexaenoic acid. See: abstract.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the method of treating skin conditions as taught by Murad et al by combining collagen in the formulation because of the reasonable expectation of obtaining a method of treating skin with an orally administered composition that ameliorates rough, dry skin while at the same time decreases fine wrinkles because "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose....[T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

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Claims 5 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murad 5,804,594 and further in view of BIKEN CORP JP 10165138 taken together with Haynes et al., 5,998,173.

Although the combination of references above teaches a method of skin care, including the reduction of skin wrinkles, the combination lacks the specific limitation of claim 21, wherein the N-acetylglucosamine is obtained by hydrolysis of chitin.

Haynes et al., teach a method of producing N-acetyl-D-glucosamine by the enzymatic hydrolysis of chitin. Haynes teaches a method of producing N-acetyl-D-glucosamine in an economic, highly efficient process by hydrolyzing chitin. See: col. 1, lines 5-10 and abstract.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the methods of skin treatment as taught by the combined references above by using N-acetyl-D-glucosamine obtained by the hydrolysis of chitin, as taught by Haynes et al because of the reasonable expectation of obtaining N-acetylglucosamine in an economic, highly efficient method by hydrolyzing natural, abundant materials to produce said N-acetylglucosamine in an environmentally friendly manner.

Claims 4, 9-12, 16, 18, 20, 22, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murad 5,804,594 and further in view of SUZUKI et al JP 08165243A taken together with Haynes et al., 5,998,173.

Murad teaches N-acetylglucosamine in an orally administered pharmaceutical composition for the treatment of skin conditions, including the treatment of skin wrinkles,

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by administering said composition in the form of capsules and tablets and containing amounts of N-acetylglucosamine that overlap those as claimed instantly in claims 5-6 and 19. See: col.1, line 25 – col. 3, line 56; col. 8, line 43 – col. 10, line 40, claims 13-19.

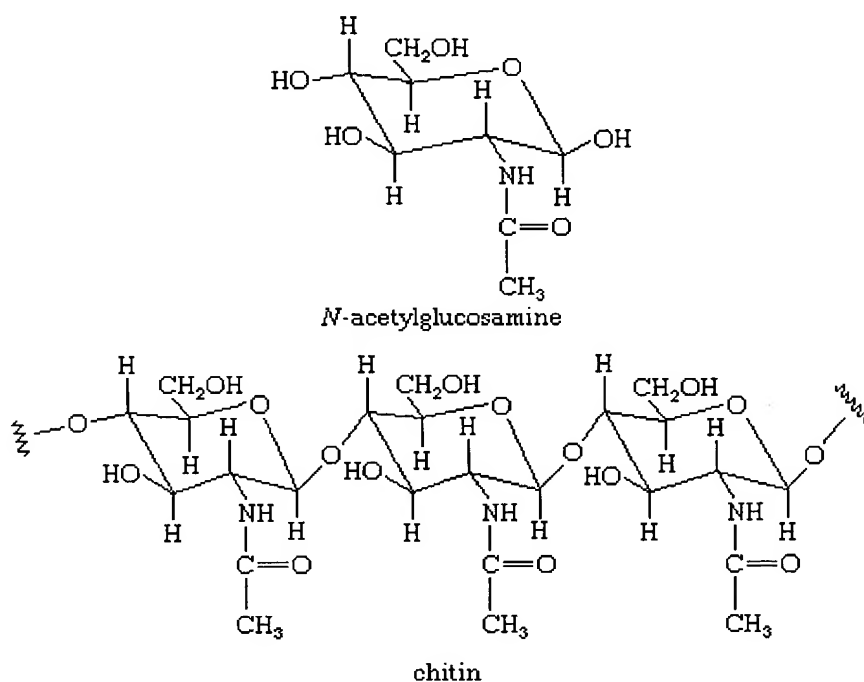
Although the primary reference teaches N-acetylglucosamine in an orally administered pharmaceutical composition for the treatment of skin conditions, including the treatment of skin wrinkles, it lacks the chitinoligosaccharide as claimed instantly in claim 4 or the method of obtaining N-acetylglucosamine, as claimed in claim 21.

SUZUKI et al teach a composition having anti-inflammatory action, which is free from side effects and which may be in the form of an oral agent. The secondary reference teaches that anti-inflammatory agent as comprising a sulfated chitinoligosaccharide.

Haynes et al., teach a method of producing N-acetyl-D-glucosamine by the enzymatic hydrolysis of chitin. Haynes teaches a method of producing N-acetyl-D-glucosamine in an economic, highly efficient process by hydrolyzing chitin. See: col. 1, lines 5-10 and abstract.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the method of skin treatment as taught by Murad by adding a chitinoligosaccharide as taught by SUZUKI et al., particularly given that chitin is a polymer of *N-acetylglucosamine*, a sugar that contains an amide functional group, and the sugar units in chitin are linked by β -1,4-glucosidic bonds:

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and the method of producing N-acetylglucosamine as taught by Haynes et al., is rate-limited by the enzyme that produces N-acetylglucosamine from chitin and the formation of chitobiose and chitotriose are secondary and tertiary products when forming N-acetylglucosamine.

Therefore one would have been motivated to add chitin oligosaccharides to the composition Murad for the added anti-inflammatory benefits of said oligosaccharides touted by SUZUKI et al and the fact that the cost efficient processes of obtaining N-acetylglucosamine of Haynes et al., teaches them as secondary and tertiary products in the formation of N-acetylglucosamine.

Furthermore obtaining N-acetylglucosamine by the hydrolysis of chitin as taught by Haynes et al., and Haynes teaches that N-acetylglucosamine is obtained by an economic, highly efficient method by hydrolyzing natural, abundant materials to produce said N-acetylglucosamine in an environmentally friendly manner. Furthermore, in

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regard to the method of claim 20, N-acetylglucosamine is the same chemical compound regardless of how it is derived.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

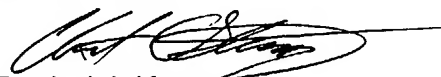
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Clinton Ostrup whose telephone number is (703) 308-3627. The examiner can normally be reached on 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Clinton Ostrup
Examiner
Art Unit 1614



Frederick Krass
Primary Examiner
Art Unit 1614

